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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,713	11/10/2003	Guenter Frey	RDID 02106US (WP21455)	6392

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EXAMINER	
HYUN, PAUL SANG HWA	
ART UNIT	**PAPER NUMBER**
1743	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/705,713	FREY ET AL.	
	Examiner	Art Unit	
	Paul S. Hyun	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/10/2003,6/30/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

REMARKS

The amended claims and specification submitted by Applicants has been acknowledged. Applicants amended claims 1-19, cancelled clams 20 and 21, and added new claim 22.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **1-3, 9-12 and 14-18** are rejected under 35 U.S.C. 102(b) as being anticipated by Brody et al. (US 5,922,210).

Brody et al. disclose a device and as well as a method for separating plasma from whole blood. The device comprises a strip-shaped first zone 5 where whole blood minus the plasma is retained, and a strip-shaped second zone 6 where plasma passes through before reaching discharge unit 7 that is perpendicular to the first and second zones (see Fig. 1 and lines 1-15, col. 4). Negative pressure can be utilized to facilitate the separation of the plasma from whole blood (see lines 20-25, col. 3). The discharge unit can be coupled to an analyzer to analyze the plasma (see lines 55-60, col. 5).

With respect to claim 2, the claim does not comprise any patentably significant limitations because the term "single-use article" is dependent on the action of the user.

Any material object can be a single-use article if the user discards the object after one use.

Claims **1-6, 8, 9, 12-14 and 18** are rejected under 35 U.S.C. 102(b) as being anticipated by Winkelman (US 3,596,652).

Winkelman discloses a device for separating plasma from whole blood as well as a method for using the device to separate plasma from whole blood. The device comprises a first zone 40, a plunger that comprises a second zone 80 and movable within the device, a trigger unit 60, and a discharge unit 30 (see Figs. 3 and 4). In operation, blood is applied to the first zone via inlet 18 by drawing the plunger away from the first zone. Once the first zone is filled with blood, the plunger is pushed back towards the first zone, at which point plasma and only the plasma passes through unidirectional valve 24 to the second zone via negative pressure (lines 1-10, col. 5). The trigger unit 60 is then actuated away/detached from the first zone to isolate the plasma and the plasma can be eluted from discharge unit 30 to be analyzed (see column 7 and Abstract).

With respect to claim 5, although the reference does not explicitly disclose that the second zone 80 is configured to rotate, given that the second zone comprises a plunger, it is apparent that it can rotate within the device while it is actuated.

Claims **1 and 7** are rejected under 35 U.S.C. 102(b) as being anticipated by Ayres (US 3,897,340).

Ayres discloses a device for separating plasma from whole blood (see Figs. 1 and 2). The device comprises a first zone separated from a second zone by a piston 18 and two filters 30 and 32. In operation, the first zone is filled with whole blood and plasma and only the plasma enters the second zone via filters 30 and 32. The plasma can be discharged through closure member 15.

Claims **12 and 19** are rejected under 35 U.S.C. 102(b) as being anticipated by Rapoza et al. (US 3,832,969).

Rapoza et al. disclose a method for separating plasma from whole blood. The method comprises the steps of providing a capillary tube adapted to hold 72 microliters of blood, filling the capillary tube, centrifuging the capillary tube to separate plasma from whole blood such that blood components are retained in one zone and plasma is retained in another zone, and transferring the plasma to.a pipette (see lines 25-55, col. 8).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims **1-16, 18 and 19** are rejected under 35 U.S.C. 102(e) as being anticipated by Marsden (US 2002/0143298 A1).

Marsden discloses a device as well as a method for separating plasma from whole blood (see Figs. 4-6). The device is adapted to process 65-110 microliters of blood (see [0046]). The device comprises a first zone 10 removably separated from a second zone 64 by filters 81 and 82. The filters are adapted to separate plasma from whole blood when pressure is applied by plunger 34. The filtered plasma is discharged through outlet 72 into analyzer 12 (see Fig. 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim **17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Marsden.

Marsden discloses that the plasma is separation is assisted by positive pressure, not negative pressure. However, it would have been obvious to one of ordinary skill in

the art to utilize negative pressure instead of positive pressure so that the blood components do not get crushed against the filters by the plunger.

Claim **22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Marsden in view of Goldberg (US 4,226,713).

Marsden discloses that the plasma can be analyzed, but the reference does not disclose that the analyte to be detected is HDL.

Goldberg discloses a method for detecting HDL in plasma (see Abstract). Detecting HDL in plasma is significant because cholesterol levels in blood are related to risk factors associated with coronary heart disease (see lines 10-15, col. 1). In light of the disclosure of Goldberg, it would have been obvious to one of ordinary skill in the art to use the method disclosed by Marsden to determine the HDL concentration in the plasma to ascertain the risk factors associated with coronary heart disease.

Claims **10, 11 and 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkelman.

Winkelman does not explicitly disclose a test element. However, the reference discloses that the device is intended to be used for isolating the plasma for analysis (see Abstract). It would have been obvious to one of ordinary skill in the art to provide the device disclosed by Winkelman with a test element for analyzing the plasma.

With respect to claim 15, although the reference does not explicitly disclose that the separated plasma is released from the second zone by means of pressure, given

that the second zone is a syringe-like device, it would have been obvious to one of ordinary skill in the art to remove the plasma from the second zone by means of pressure. It is well-known in the art to remove the contents of a syringe via pressure.

Claims **7, 16 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkelman in view of Ayres.

The device disclosed by Winkelman does not comprise a fleece to isolate the plasma. Instead, it relies on precise movement of the plunger to prevent blood components from entering the second zone.

Ayres discloses a device for separating plasma from whole blood wherein the separation is accomplished by means of two filters 30 and 32. In light of the disclosure of Ayres, it would have been obvious to one of ordinary skill in the art to provide the device disclosed by Winkelman with filters and to filter the blood to provide a simpler and accurate means to prevent blood components from entering the second zone.

Claim **22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Winkelman in view of Goldberg (US 4,226,713).

Winkelman discloses that the plasma can be analyzed, but the reference does not disclose that the analyte to be detected is HDL.

Goldberg discloses a method for detecting HDL in plasma (see Abstract). Detecting HDL in plasma is significant because cholesterol levels in blood are related to risk factors associated with coronary heart disease (see lines 10-15, col. 1). In light of

the disclosure of Goldberg, it would have been obvious to one of ordinary skill in the art to use the method disclosed by Winkelman to determine the HDL concentration in the plasma to ascertain the risk factors associated with coronary heart disease.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PSH
12/26/06

YELENA GAKH
PRIMARY EXAMINER